ABC Diversion Control Program

The Sales Associate Role in Diversion Control

Regulatory Responsibility

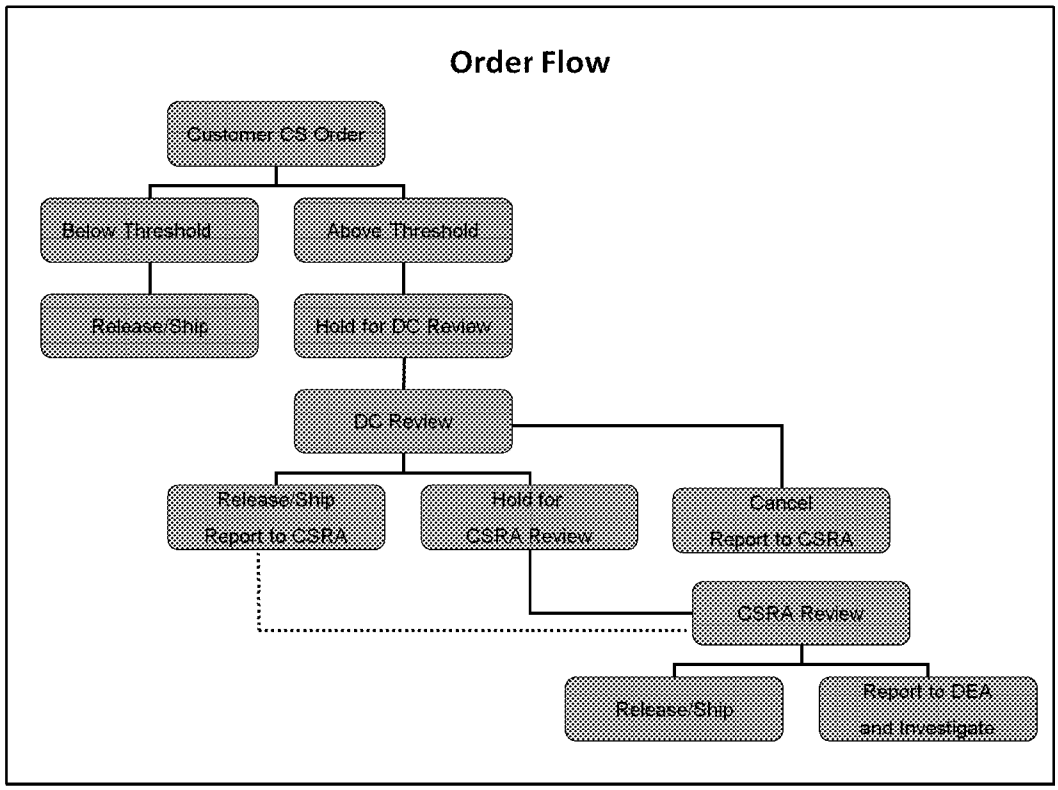
Title 21 of the Code of Federal Regulations:

1301.71(a) – "All applicants and registrants shall provide **effective controls** and **procedures** to guard against theft and diversion of controlled substances."

Distributors viewed as a "choke point."

Regulatory Responsibility

- **21 CFR 1301.74** requires that registrants design and operate systems to identify suspicious **orders** and report suspicious **orders** to DEA when discovered.
- Reporting suspicious orders to DEA does NOT relieve the distributor of the responsibility to maintain effective controls to prevent diversion.
- DEA cannot tell a distributor if an order is legitimate or not and usually will not tell the distributor whether or not to ship.
- Distributor must make a "business decision" whether or not to ship the order.



Order Monitoring Program

- Customers classified according to DEA business activity.
- Total monthly dollar volume = customer size
- Thresholds = average of products dispensed of like classified customers + 300%.
- Thresholds are continually evaluated based on variables such as business model, location, specialties, etc.

What is a suspicious order?

- Is the quantity being ordered unusually large?
- Does the order deviate substantially from a normal pattern?
- Is the frequency of the order unusual?
- Is the item(s) being ordered high-risk, or prone to diversion?

Suspicious Order Investigation

- Order flagged by OMP
- Unusual size, deviates substantially from a normal pattern, unusual frequency, item type.
- Purchase history.
- Dollar volume/product mix.
- Ratio of CS to Non-CS purchases.
- Contact with customer.
- Is there a rationale for the order?
- Site visit.
- Responsibility not to ship a suspicious order.

CSRA Investigation and Status

- As currently configured, orders that are sent to CSRA for investigation are uploaded to Metastorm about once an hour.
- CSRA reviews orders from 7 AM Eastern until approximately 10 PM Eastern.
- If CSRA approves an order for release, the DC will be notified by automated E-mail.
- If CSRA rejects an order that will be reported to the DEA as suspicious, the order will be held in the queue.

CSRA Investigation and Status

- Orders reported as suspicious are uploaded to DEA HQ at 3 PM eastern each day.
- The process will change with the SAP deployment and the procedure will be updated as that occurs.

Requests for Threshold Review

- Requests for threshold review should be submitted by the ACM or other responsibility to the Director – Diversion Control Program.
- The request must be made in writing using the proper form which can be found on the CSRA web site or Street Smart.

Criteria for Threshold Review

Based upon sales volume and controlled substance (CS) ratio, CSRA has been able to place all retail pharmacy accounts into one of four categories, which determines how CSRA will approach adjustments to the account's established threshold levels.

Criteria for Threshold Review

Initial threshold levels for Retail Pharmacy Accounts are currently established by size:

Retail Small – Total monthly dollar volume < $99 K.
Retail Medium – Total monthly dollar volume $100K - $249,999.
Retail Large – Total monthly dollar volume > $250K.

1) Low Dollar Volume / Low CS Ratio: Customers in this category are likely to be newly established accounts. CSRA will consider raising threshold levels within reason as long as total monthly dollar volume rises along with its CS volume.

2) High Dollar Volume / Low CS Ratio: Customers in this category are generally Primary Accounts and not a concern. Threshold levels can be raised once justification is provided.

3) **High Dollar Volume / High CSRatio**: Customers in this category are generally Primary Accounts that specialize in Pain Management. Since these accounts already purchase a high percentage of controlled substances (over 40%), CSRA will not increase current threshold levels on these accounts without an extensive review of the account's file which may require an on-site inspection.

4) Low Dollar Volume / High CS Ratio: Customers in this category are generally Secondary Accounts, and account for the majority of the OMP issues. Sales, the VP/DCM, and potentially the RVP should closely evaluate the business decision to service these accounts:

a.) is there a potential to transition this secondary account to primary; or

b.) is ABC assisting/enabling its competitor's to retain primary accounts by providing these accounts with "high risk" controlled substances because the primary distributor has limited the account's controlled substance quantities to limit its exposure?

CSRA will not increase threshold levels on these accounts unless there is: an increase in the customer's total monthly dollar volume; a decrease in CS ratio; an extensive review of the account file; and most likely an on-site inspection.

New Customer Due Diligence

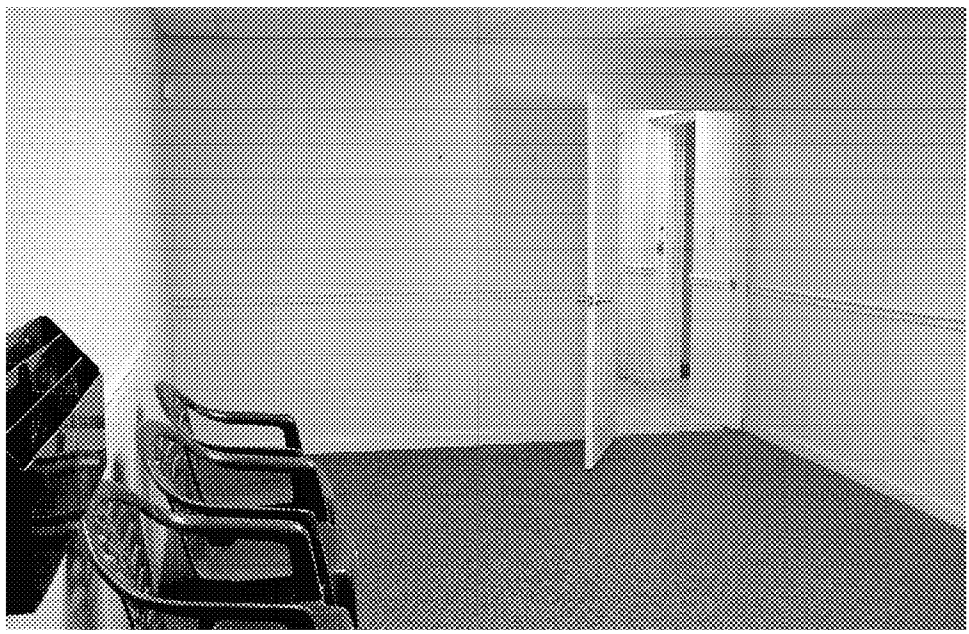
- The questions are there for a reason – Answer all!
- Unanswered questions slow the process.
- Q5 – Start up, Existing Business, Suppliers.
- Q8 – Full disclosure.
- Q10 – 14 – Ownership.
- Q22 – Distribution and the retail pharmacy.
- Q31 – Unless a start-up should have data.
- Signatures / photographs

Red Flag

Red Flag

Red Flag

Red Flag



Coming to a State Near You!

Corporate OMP Contacts

- Ed Hazewski – 610-727-3680
  After hours emergency – 302-584-2932
- Dave Breitmayer – 610-727-7223
- Kevin Kreutzer – 610-727-2726
- Joe Tomkiewicz – 815-221-3612 (Chicago DC)